IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiff,	)	**C.A. No. 07 civ 8002 (SHS)**
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

DEFENDANTS APOTEX, INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Apotex, Inc., and Apotex Corp. ("Defendants") answer the Complaint for Patent Infringement of Purdue Pharma., L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals, L.P. ("Plaintiffs" or "Purdue") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Purdue purports to bring an action under the patent laws of the United States, Title 35; however it is denied that any such claim can be sustained.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

ANSWER: Admitted.

3. This Court has personal jurisdiction over defendant Apotex, Inc. and Apotex Corp. (collectively, "Apotex") because, on information and belief, Apotex is doing business throughout the United States, including within this judicial district.

ANSWER: Apotex, Inc. denies that it conducts business throughout the United States. Admit that Apotex Corp. does do business throughout the United States. Apotex, Inc. and Apotex Corp. admit that they have consented to personal jurisdiction in this judicial district for this matter; otherwise denied.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b),(c), and (d), and 1400(b).

ANSWER: Admitted.

THE PARTIES

5. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard Stamford, Connecticut 06901-3431. Purdue Pharma is an assignee of the patent in suit identified in paragraph 10 below, and markets and sells in the United States the controlled-release oxycodone hydrochloride pain relief medication OxyContin® Tablets ("OxyContin®").

ANSWER: Apotex, Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 5 of the Complaint, and therefore deny same.

6. Plaintiff the P.F. Laboratories Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey 07512. P.F. Labs is an assignee of the patent in suit identified in paragraph 10 below and manufacturers OxyContin® in the United States.

ANSWER Apotex, Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 6 of the Complaint, and therefore deny same.

7. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware,

having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893. Purdue Pharmaceuticals is an assignee of the patent in suit identified in paragraph 10 below and manufactures OxyContin® in the United States.

ANSWER: Apotex, Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 7 of the Complaint, and therefore deny same.

8. Upon information and belief, defendant Apotex Inc. is a Canadian corporation, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Admitted and stated further that Apotex, Inc. has a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada.

9. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted and stated further that Apotex Corp. has a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

THE PATENT IN SUIT

10. Plaintiffs are the lawful owners of all right, title, and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (Approved Drug Products With Therapeutic Equivalence Evaluation) as covering OxyContin® and contains one or more claims covering OxyContin®'s method of use:

United States Patent No. 5,508,042, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("the '042 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on April 16, 1996 naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors.

ANSWER: Apotex, Inc. and Apotex Corp. admit that U.S. Patent No. 5,508,042 ("the '042 patent") is entitled "Controlled Release Oxycodone Compositions" and that a document purporting to be a copy of the '042 patent is attached as Exhibit A. Apotex, Inc. and Apotex Corp. further admit that the issue date listed on the exhibit purporting to

be the '042 patent is April 16, 1996, and that the exhibit purporting to be the '042 patent lists Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as inventors. Apotex, Inc. and Apotex Corp. deny that the '042 patent was duly and legally issued. Apotex, Inc. and Apotex Corp. are without sufficient information or knowledge to form a belief as to the remainder of the paragraph, and therefore denies the same.

11. Upon information and belief, Apotex submitted Abbreviated New Drug Application ("ANDA") No. 78-840 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of Oxycodone Hydrochloride CT Tablets 10, 20, 40, and 80 mg ("Apotex's Tablets"), a generic version of Purdue's OxyContin®, before the expiration of the '042 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. submitted an Abbreviated New Drug Application ("ANDA") number 78-840 to the FDA to market a generic version of a drug product with the proprietary name Oxycontin.

12. Upon information and belief, Apotex's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(vii)(IV) alleging that the '042 patent, listed in the FDA's Orange Book as covering the reference listed drug OxyContin®, is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's Tablets.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. submitted an ANDA which contained a paragraph IV certification.

13. In a letter dated August 1, 2007 addressed to Plaintiff Purdue Pharma and "Euro-Celtique, S.A.," Apotex sent "notice" with respect to its 10, 20, 40 and 80 mg Tablets and the '042 patent under 21 U.S.C. §355(j)(2)(B)(ii) ("Apotex's notice"). Purdue Pharma received Apotex's notice on or about August 2, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. sent a letter dated August 1, 2007, to Purdue Pharma and Euro-Celtique, S.A. with respect to the '042 patent. Apotex, Inc. and Apotex Corp. state that they are without sufficient knowledge or

information to form a belief as to the truth of the remaining averments, and therefore deny the same.

14. Apotex's notice does not provide any valid basis for concluding that the '042 patent is invalid, unenforceable, and/or not infringed.

ANSWER: Apotex, Inc. and Apotex Corp. deny this allegation.

15. Upon information and belief, the method of the use of Apotex's Tablets is covered by one or more claims of the '042 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny this allegation.

16. Upon information and belief, Apotex's submission of its ANDA was an act of infringement of the '042 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

ANSWER: Apotex, Inc. and Apotex Corp. deny this allegation.

17. Upon information and belief, Apotex's commercial manufacture, use, sale, and/or offer for sale of its Tablets would infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '042 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny this allegation.

18. Upon information and belief, Apotex has been aware of the existence of the '042 patent, and has no reasonable basis for believing that Apotex's Tablets will not infringe the '042 patent, thus rendering the case "exceptional," as that term is 35 U.S.C. § 285.

ANSWER: Apotex, Inc. and Apotex Corp admit that they were aware of the existence of the '042 patent when Apotex, Inc. filed ANDA No. 78-840; otherwise denied.

19. The acts of infringements by Apotex set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by the Court.

ANSWER: Apotex, Inc. and Apotex Corp. deny this allegation.

WHEREFORE, defendants pray that Plaintiffs take nothing from this action, and that its complaint be dismissed with prejudice, with costs assessed against Plaintiffs.

AFFIRMATIVE DEFENSES

Apotex, Inc. and Apotex Corp. set forth the following affirmative and other defenses. In each defense, Apotex, Inc. and Apotex Corp. adopt by references, repeats, and realleges its responses in paragraphs 1-19 above as if fully set forth therein.

Apotex, Inc. and Apotex Corp. do not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Purdue bears the burden.

FIRST DEFENSE: FAILURE TO STATE A CLAIM

20. The complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE: INVALIDITY

21. The claims of the '042 patent are invalid and/or unenforceable on grounds specified in United States Code, Title 35, including, but not limited to the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD DEFENSE: NON-INFRINGEMENT

22. The manufacture, use, offer to sell, sale, and/or importation of the product that is the subject of Apotex, Inc.'s ANDA 78-840 has not infringed, does not infringe, and will not infringe (either directly, contributorily or by inducement) any enforceable claim of the '042 patent.

FOURTH DEFENSE: INEQUITABLE CONDUCT

23. Each and every claim of the '042 patent is unenforceable because these claims were procured through multiple acts of inequitable conduct by Purdue and/or its

affiliate, the inventors of the '042 patents, and/or Purdue's attorneys, during the prosecution before the United States Patent and Trademark Office ("PTO"), of the series of related and co-pending applications that resulted in the '042 patent including, but not limited to:

a. misrepresenting Dr. Kaiko's "insight" that a controlled release oral formulation of oxycodone would reduce by half the required dosage range to control pain in 90% of patients compared to the dosage of a controlled release oral formulation of morphine, as a sound scientific "discovery" supported by experimentation and clinical results;

b. misrepresenting that the so-called "discovery" of a reduced dosage range for controlled release oral oxycodone was "surprising" when in fact it was already known in the prior art that orally administered oxycodone in an " " formulation is twice as potent as orally administered morphine in an " " formulation, which would render it obvious to one of ordinary skill in the art that use of a reduced dosage of oxycodone compared to morphine in a controlled release formulation would likely be successful;

c. failing to disclose to the PTO the prior art references showing that orally administered oxycodone in an " " formulation is twice as potent as orally administered morphine in an " " formulation;

d. misrepresenting that a dosage range of 10 mg to 40 mg of oxycodone in a controlled release oral formulation (the cited 4-fold dosage range) was analgesically equivalent to a dosage range of 10 mg to 80 mg of morphine in a controlled release oral formulation (the cited 8-fold dose)

e. failing to disclose *actual* clinical data, obtained from studies sponsored by Purdue and submitted to the FDA, that directly contradicted Dr. Kaiko's "insight" and established that, for the effective treatment of pain, the claimed controlled release oral oxycodone formulation did *not* result in a reduced dosage range of oxycodone as compared to controlled release oral morphine;

f. failing to disclose to the PTO that the so-called "surprising discovery" of a reduced dosage range relied on to overcome the obviousness rejection during the prosecution of the '331 patent was based on the "insight" of Dr. Kaiko, who was not a named inventor in the '331 patent.

g. misrepresenting that it was "surprising" that the drug release rate obtained in the claimed controlled release oral oxycodone formulation also had a maximum plasma level (T_{max}) of 2 – 4 hours when in fact, Purdue had previously developed 4 other controlled release oral opioid formulations with both the same drug release rate and the same (T_{max}) of 2 – 4 hours;

h. failing to disclose each of the prior art patents or public disclosures, owned by Purdue, for those other controlled release oral opioid formulations with both the same drug release rate and the same (T_{max}) of 2 – 4 hours as the claim formulation; and,

i. failing to disclose the relationship between Purdue, Euro-Celtique, the named inventors of the '331 patent and Dr. Kaiko who was presented to the PTO during prosecution of he '331 patent as an independent expert rather than a colleague of the named inventors and as the very person who came up with the so-called "surprising discovery" relied on to overcome the obviousness rejections made in the '331 patent application.

24. These multiple misrepresentations and repeated failures to disclose relevant prior art occurred repeatedly throughout the prosecution of the patents that led up to the allowance of the '042 patent and alone and in combination are sufficient to establish inequitable conduct on the part of Purdue and the unenforceability of the '042 patent .

25. The following U.S. Patents and the conduct of Purdue, Euro-Celtique, and/or the respective applicants and assignees during their prosecution are relevant to this affirmative defense and the unenforceability of the '042 patent:

a. U.S. Patent 4,861,598 ("the '598 patent"), resulted from U.S. Application Serial No. 887,340 ("the Oshlack '340 Application") filed July 18, 1986 and issued August 29, 1989. The '598 Patent names Benjamin Oshlack as the sole inventor and is assigned on its face to Euro-Celtique S.A.

b. U.S. Patent 4,970,075 (the '075 patent) resulted from U.S. Application Serial No. 333,309 filed April 5, 1989 as a divisional application of the Oshlack '340 Application and issued November 13, 1990 with a terminal disclaimer to the '598 Patent. The '075 Patent names

Benjamin Oshlack as the sole inventor and is assigned on its face to Euro-Celtique S.A.

c. U.S. Patent 5,266,331 (the '331 patent) resulted from U.S. Application Serial No. 07/800,509 filed November 27, 1991 and issued November 30, 1993 with a terminal disclaimer to U.S. Patent 4,990,341 ("the Goldie '341 Patent); the 'Goldie '341 Patent was also assigned on its face to Euro-Celtique. The '331 Patent names Benjamin Oshlack, John Minogue and Mark A. Chasin as the alleged inventors and is assigned on its face to Euro-Celtique S.A.

d. U.S. Patent No. 5,549,912 (the '912 patent) resulted from U.S. Patent Application Serial No. 81,302 filed on November 25, 1992 as a continuation-in-part of the '331 Patent and issued August 27, 1996 with a terminal disclaimer to the '331 Patent.

e. U.S. Patent No. 5,508,042 (the '042 patent) resulted from U.S. Patent Application Serial No. 467,584 filed on June 6, 1995 as a divisional application of the '912 Patent and issued on April 16, 1996. While the '042 Patent was being prosecuted, the applications for the '912 and '295 Patents were co-pending before the PTO.

f. U.S. Patent No. 5,656,295 (the '295 patent) resulted from U.S. Patent Application Serial No. 618,344 filed on March 19, 1996 as a continuation-in-part of the '912 Patent and issued on August 12, 1997 with a terminal disclaimer to the '331 Patent.

26. Purdue listed the six patents identified in paragraph 25 in the FDA's 'Orange Book' (Approved Drug Products With Therapeutic Equivalence Evaluation), as covering Purdue's OxyContin®.

27. Each of the patent applications of paragraph 25 listed Euro-Celtique S.A. ("Euro-Celtique) as the assignee during prosecution before the PTO.

28. Euro-Celtique is an affiliate of Purdue that is often the entity in whose name Purdue prosecuted patent applications.

29. The actions of Euro-Celtique during prosecution of the applications discussed herein are attributable to Purdue. The designations Purdue and Euro-Celtique

will be used interchangeably when discussing the conduct of the respective applicants and assignees during the prosecution of these applications.

30. The '912, '042 and '295 Patents, collectively referred to herein as "the '912 Patent Family", all name Benjamin Oshlack, John Minogue, Mark A. Chasin and Robert F. Kaiko as the inventors.

31. The '598, '075 and '331 patents are prior art to the '912 Patent Family, including the asserted '042 patent.

32. The '912 patent was claimed to be a continuation-in-part from the '331 patent and Purdue claimed the benefit of the filing date of the '331 patent.

33. None of the claims of the '912 patent are supported by the original disclosure of the '331 patent, but rather are only supported by the new matter added to disclosure when the application was filed.

34. The '912 patent is not entitled to the benefit of the filing date of the '331 patent. Instead, the '331 patent is prior art to the '912 patent.

Misrepresentations and Failures to Disclose Relevant Prior Art Related to the So-Called "Surprising Discovery" of a Reduced Dosage Range:

35. Purdue and its affiliate's first reference to its so-called "surprising discovery" that the claimed controlled release oral formulation of oxycodone would reduce by half the required dosage range to provide pain relief to 90% of patients compared to the dosage of a controlled release oral formulation of morphine was made during the prosecution of the '331 Patent.

36. Purdue referred to this "surprising discovery" multiple times during not only the prosecution of the '331 patent but also while prosecuting the '912 Patent Family.

37. This "surprising discovery" was relied on by Purdue in its responses and in telephonic interviews with the patent Examiners in charge of the various applications as a basis for overcoming obviousness rejections by the Examiners.

38. The terminology "surprising" is generally used to show that the result in question would not have been obvious to one of ordinary skill in the art; i.e., it would have been "surprising" to one of ordinary skill in the art. Such claims are generally supported by declarations or affidavits by disinterested third party experts to support an argument over an obviousness rejection.

39. Purdue failed to disclose to the PTO that there were multiple prior art references showing that it was well known that orally administered oxycodone in an formulation is twice as potent as orally administered morphine in an formulation.

40. Kathleen M. Foley, M.D. published in *1985* an extensive article (Foley, *N. Engl. J. Med.*, (1985) 313:84-95) dealing with the treatment of cancer pain in which she provided a table (Table 6, page 90) showing equianalgesic doses of orally administered narcotics for severe pain. That table shows that equianalgesic doses of orally administered morphine and orally administered oxycodone are 60 mg and 30 mg, respectively.

41. The Foley article is prior art to the '331 Patent and the '912 Patent Family. The Foley article disclosed that orally administered oxycodone had twice the potency of orally administered morphine.

42. Purdue was aware of the Foley publication.

43. Dr. Kaiko was personally aware of the Foley article and the fact that orally administered oxycodone was twice as potent as orally administered morphine, at least

because he cited that Foley article in one of his own publications and had published with Foley on numerous prior occasions.

44. The Foley article as well as additional prior art taught that one of ordinary skill in the art could predictably achieve an equal amount of pain relief in a given population of patients with one-half the dose of orally administered oxycodone compared to that of orally administered morphine, due to the fact that oxycodone was known to be twice as potent during oral administration.

45. Dr. Kaiko reported on the two-fold potency difference between oxycodone and morphine in his memo dated July 16, 1990 to Goldenheim, Sackler and Friedman in which he stated, *inter alia,* that "[b]y extrapolation, one might predict that 30 mg p.o. oxycodone is equivalent to between 30-60 mg p.o. morphine".

46. Based on the teachings of the prior art, one of ordinary skill in the art could determine that if it takes 10-80 mg orally twice a day to control pain using morphine, the same pain controlling effect could be achieved with 5-40 mg of oxycodone orally twice a day.

47. Contrary to Purdue's assertions, the equianalgesic dosing ranges predicted from the prior art of 10-80 mg for morphine and 5-40 mg for oxycodone are both eight-fold ranges.

48. A 5 mg tablet of oxycodone (Roxicodone®) was known and commercially available at the time of prosecution of the '331 patent and the '912 Patent Family.

49. Purdue did not include in the disclosures for the '331 patent or the ' 912 Patent Family the 5 mg dose of oral oxycodone that is equianalgesic to a 10 mg of oral morphine.

50. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Purdue chose to ignore the 5 mg dosage in order to claim the so-called reduction of dosage range from 8-fold for morphine to 4-fold for oxycodone.

51. Purdue relied on the asserted reduction from an 8-fold range to a 4-fold range to support an additional benefit of the invention of reducing the time needed by medical personal to titrate the correct dosage for a particular patient.

52. The terminology "discovery" by itself or particularly when used with the past tense, implies that actual experimentation and/or clinical trials were run.

53. Purdue consistently used both the term "discovery" and the past tense when asserting the discovery of a reduced dosage range for its claimed controlled release oral oxycodone formulation.

54. During discovery in another patent infringement action brought by Purdue, Purdue admitted that there had been no actual experimentation or clinical trials showing the claimed controlled release oral oxycodone formulation actually resulted in a reduction by half of the dosage range required to provide pain relief to 90% of patients, as compared to the dosage of a controlled release oral formulation of morphine. Purdue admitted that this "discovery" was an "insight" of Dr. Kaiko.

55. This insight of Dr. Kaiko is relied on to support patentability of the '331 patent; however Dr. Kaiko is not a named inventor of the '331 patent.

56. The term "insight" is generally used to indicate deductions made based upon known information, knowledge and/or expertise but *not* supported by any experimental or clinical studies.

57. Purdue also failed to disclose that it had sponsored actual clinical studies of the claimed controlled release oxycodone formulation and that these studies contradicted the "insight" of Dr. Kaiko and established that, for the effective treatment of pain, the claimed controlled release oxycodone formulations did *not* result in a reduction by half of the dosage range required to provide pain relief to 90% of patients, as compared to the dosage of a controlled release oral formulation of morphine.

58. The clinical studies referenced in paragraph 57 were conducted concurrently with the prosecution of the '912 Patent Family.

59. The studies referenced in paragraph 57 were later published by Purdue in journals relevant to the field of pharmaceutical science.

60. Purdue submitted the studies referenced in paragraph 57 to the FDA while seeking approval of its claimed controlled release oral oxycodone formulation.

61. Purdue never disclosed the studies referenced in paragraph 57 to the PTO.

62. The studies referenced in paragraph 57 include, but are not limited to, the "Kalso study" (approved by Dr. Kaiko and finding that controlled release oxycodone was judged to provide cancer patients with effective pain control that was clinically equivalent to that provided by controlled release morphine); and the "Berman study" (where Dr. Kaiko co-authored the article that concluded that "oral CR oxycodone was as effective as oral CR morphine for controlling chronic cancer pain" and pointing out similarities between CR oxycodone and CR morphine with regard to time necessary for effective dose titration).

63. Dr. Kaiko's own emails with colleagues demonstrate his knowledge of the Kalso study and his awareness of the prior art showing that oxycodone generally had

twice the potency of morphine. In an email sent by Dr. Kaiko on August 22, 1996, he stated that "we do have better evidence that a 1:2 dose [of oxycodone to morphine] is equianalgesic." Dr. Kaiko states later in the email that "we need to explain that at the time the study was designed, we were using the ratio suggested in the literature by the Kalso study rather than the ratio of 2:1 suggested by the earlier literature and more recently confirmed in our own relative potency study".

64. Dr. Kaiko clearly knew that the findings of the Kalso study were contradictory to earlier literature that suggested a 2:1 ratio of morphine to oxycodone.

65. There were also multiple articles published after the issuance of the '912 Patent Family that confirmed this absence of a reduced dosage range for treatment of pain with CR oxycodone.

66. These articles include, but are not limited to, "Comparative Clinical Efficacy and Safety of a Novel Controlled-Release Oxycodone Formulation and Controlled-Release Hydromorphone in the Treatment of Cancer Pain", co-authored by an employee of Purdue Frederick in Canada; Hesitance and Kalso; "Controlled-release oxycodone and morphine in cancer related pain", published in the journal *Pain* in 1997 reporting findings from a study supported by Purdue Frederick that finds that fewer patients were successfully titrated with CR oxycodone compared to CR morphine, another result that directly contradicts the "insight" of Purdue that allowed claims for a controlled-release oxycodone formulation used in the treatment of pain; Citron, "Long-Term Administration of Controlled-Release Oxycodone Tablets for the Treatment of Cancer Pain", co-authored by Dr. Kaiko and the study conducted and sponsored by Purdue Pharma, L.P., finding that the reported range of CR oxycodone used for effective

treatment of pain is not four-fold, but rather is between a 17-20 fold range of daily dosage necessary.

Specific References to this "Surprising Discovery":

Prosecution of the '331 Patent:

67. The '331 patent application claimed in part the controlled release formulation disclosed in the Goldie '341 Patent.

68. In the '331 patent disclosed and claimed use of oxycodone as the active ingredient rather than the hydromorphone claimed in the Goldie '341 application.

69. Purdue disclosed the Goldie '341 application to the PTO.

70. All pending claims in the '331 patent application were initially rejected as obvious under 35 U.S.C. §103. The Examiner stated that it would have been obvious to use oxycodone, which was disclosed in the '598 patent, in the controlled release formulation disclosed in the Goldie '341 Patent.

71. The '598 patent was owned by Euro-Celtique, but was not disclosed to the PTO in either the '331 application itself, or in the information disclosure statement filed by Euro-Celtique in the '331 application.

72. In response to the obviousness rejection, Euro-Celtique distinguished the claimed controlled release oxycodone formulation from the formulation of the Goldie '341 patent by claiming the so-called "surprising discovery" set out in paragraphs 35 – 66.

73. Euro-Celtique specifically stated that the recited oxycodone formulation in the '331 patent application had the "surprising" effect of controlling pain over a "*substantially narrower, approximately four-fold* [range] (10 to 40 mg over 12 hours –

around-the-clock dosing) in approximately 90% of patients," in contrast to the approximately eight-fold range (10 to 80 mg over 12 hours) required for approximately 90% of patients for opioid analgesics in general.

74. On or about February 3, 1993, the PTO Examiner properly maintained the obviousness rejection in light of the Goldie '341 and '598 patents with respect to pending claims 14-17.

75. Euro-Celtique then had a telephone interview with the Examiner and in response to the Examiner's request filed an amendment on or about March 10, 1993. The amendment included the affidavit of Robert F. Kaiko and attached to that affidavit was an exhibit supporting the asserted the "surprising" reduction in dosage range for the claimed formulation.

Prosecution of the '912 patent:

76. The '912 patent was filed as a continuation-in-part of the '331 patent. The '331 and the '912 patents were co-pending for over one year.

77. The '331 and '912 patent applications were handled by separate Examiners.

78. The '912 patent application pursued the claims in the original application draw to the controlled release oral oxycodone composition.

79. The claims (claims 1-2) in the original application drawn to a method of use of the formulation were the subject of a restriction requirement and were later prosecuted as the '042 patent.

80. On or about August 22, 1994, the Examiner rejected the elected formulation claims of the '912 application as being anticipated by the Goldie '341 patent.

81. The applicants' responded to the Examiner's rejection by stating that it was an error due to the fact that the '341 patent is specifically directed to hydromorphone, whereas the claim invention was directed to oxycodone, an opioid analgesic not mentioned in the Goldie '341 patent.

82. Purdue also asserted the same so-called "surprising discovery" that had already been presented in the '331 patent—that pain could be controlled by the claimed oxycodone CR formulation with "1/2 the dosage range as compared to commercially-available controlled release morphine formulations to control 90% of patients with significant pain."

83. The response filed to this office action also claimed, pursuant to U.S.C. § 120, the benefit of the earlier filing date of the '331 patent.

84. This claim was made by an amendment to the '912 patent specification. At the time the amendment was made, all of the pending claims of the '912 patent were directed to new matter. Therefore, the pending claims were *not* entitled to the benefit of the earlier filing date of the '331 patent; the '331 patent was actually prior art to the '912 patent under 35 U.S.C. §102(e). Purdue was aware of this at the time that amendment was made.

The Prosecution of the '042 Patent:

85. The '042 patent issued less than one year from its filing date. The Patent Examiner who handled the application was Edward J. Webman, the same Examiner that examined the parental '912 patent.

86. The '042 patent claims a method for "reducing the range in daily dosages required to control pain" using the composition of the '912 claims.

87. The claims in the '042 patent are highly similar and only differ in the introductory phrases as shown below:

> ('042 Claim 1) A method for reducing the range in daily dosages required to control pain in human patients, comprising administering an oral . . .
>
> ('042 Claim 2) A method for reducing the range in daily dosages required to control pain in *substantially all* human patients, comprising administering an oral solid . .

88. In the first Office Action, no art was cited against the claims. However, the claims were objected to and rejected under the first and second paragraphs of Section 112 as being not properly enabled for failing the written description requirement for setting forth only optional ingredients in the vehicle, and as being indefinite for failing to specify ingredients in the delivery vehicle. No amendments or arguments were made that addressed this basis objection or rejection.

89. An interview with the Examiner was subsequently held and the claims were allowed after an agreement was reached to delete the word "substantially" from each claim, as both claims as originally submitted claimed "[a] method for *substantially* reducing the range in daily doses …".(Emphasis added.) It was not made clear how the removal of the descriptive term 'substantially' from the original claims addressed the stated §112 rejections and improved the application's chances for allowance.

90. Purdue still did not disclose to the PTO clinical studies that showed that administering the formulation of the '912 patent did not, in fact, result in "reducing the range in daily dosages required to control pain in human patients" as recited in each of the claims of the '042 patent.

91. Disclosure of this fact would have required the method of the '042 patent to be acknowledged to be inoperable.

92. The claimed method of the '042 patent does not reduce "the range in daily dosages required to control pain."

93. Disclosure of this fact would have shown the method of the '042 patent to be nothing more that a method for swallowing controlled release oxycodone tablets to control pain. Such a method is obvious in view of the prior art.

Misrepresentations and Failures to Disclose Relevant Prior Art Related to Purdue's Assertion That it was "Surprising" That the Drug Release Rate Obtained in the Claimed Controlled Release Oral Oxycodone Formulation Also had a Maximum Plasma Level (T_{max}) of 2 – 4 hours and (T_{max}) cannot be predicted based upon *in vitro* dissolution parameters :

94. During prosecution of the '331 patent Purdue asserted yet another "surprising" result due to the claimed controlled release oral oxycodone formulation. In the response filed to the second office action rejecting the claims as obvious, Euro-Celtique stated that the disclosed *in vivo* peak plasma levels (T_{max}) obtained by using oxycodone instead of hydromorphone was surprising and could not have been determined from the *in vitro* dissolution rate for oxycodone disclosed in the prior art '598 patent.

95. Euro-Celtique stated that "it is totally impossible to predict what dissolution rates for any particular drug will give rise to an extended duration of action, e.g., a 12 hour duration of action as set forth in this case," and that "[e]ven in the case of closely related drugs, predictability is impossible. . ." so that the release rate of oxycodone in the claimed controlled release oral could not have been "predicted based upon the teaching of Goldie et al."

96. Applicants also submitted an affidavit of Robert F. Kaiko to support this argument. This affidavit made statements that one of ordinary skill in the art could not

predict from *in vitro* dissolution rates that the peak plasma levels (T_{max}) of oxycodone should occur, *in vivo,* two to four hours post-administration.

97. Dr. Kaiko was identified as "a person truly skilled in this art . . . ," and an officer and employee of Purdue. Euro-Celtique did not, in any way, disclose to the PTO any connection between Dr. Kaiko, the named inventors of the '331 patent, the '331 patent or its related technology.

98. Euro-Celtique did not disclose that it was an affiliate of Purdue or that Dr. Kaiko was named as a co-inventor on the '912 application, which was a continuation-in-part of the '331 patent.

99. Euro-Celtique did not disclose to the PTO that its argument was directly contrary to the teaching of the prior art '598 patent, also assigned to Euro-Celtique.

100. Oshlack an inventor of the '598 patent is also an inventor of the '331 patent and the '912 Patent Family. Oshlack was aware that the '598 patent in fact teaches that in *vitro* dissolution data *are* predictive of the peak plasma levels (T_{max}) *in vivo*.

101. Euro-Celtique did not disclose to the PTO that it knew of other extended release opioid products each having similar *in vitro* dissolution rate ranges that also showed an extended duration of action with a T_{max} of 2 to 4 hours or that these other extended release opioid products were prior art that had been developed by Euro-Celtique.

102. Neither Euro-Celtique nor Purdue disclosed U.S. Patent 4,834,984 ("the Goldie '984 Patent") to the PTO.

103. The Goldie '984 Patent resulted from U.S. Application Serial No. 52,584 filed May 19, 1987 and issued May 30, 1989. The Goldie '984 Patent names Robert S.

Goldie, Sandra T.Z. Malkowska, Stewart T. Leslie, and Ronald B. Miller as inventors. The inventors of the Goldie '984 patent are the same inventive entity as that of the Goldie '341 patent, with both patents assigned to Euro-Celtique.

104. The Goldie '984 patent is prior art to the '331 Patent and the '912 Patent Family.

105. The *in vitro* dissolution rate ranges for the controlled-release dihydrocodeine disclosed in the Goldie '984 patent overlap with the disclosed *in vitro* dissolution rate ranges in the '331 patent and '912 Patent Family, as well as the ranges disclosed in the '598 and Goldie '341 patents.

106. The formulation disclosed in the '984 patent showed the same extended duration of action and the so-called "surprising" T_{max} of 2 to 4 hours.

107. During prosecution of the '331 and '912 patents, Purdue argued for patentability by asserting that a T_{max} of 2 to 4 hours was "surprising" for a 12-hour controlled release opioid, when in fact it was an end result of the *in vitro* dissolution rate range achieved by the controlled-release formulation disclosed by the undisclosed Goldie '984 patent.

108. The discovery of a T_{max} of 2 to 4 hours more than one year before the filing of the applications for the '331 Patent or '912 Patent Family is described in several prior art disclosures, including, but not limited to, the Goldie '984 patent (Col. 2, lines 18-21 stating "the present inventors have surprisingly found that, in the case of dihydrocodeine, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief…"), the Goldie '341 patent (Col 2, lines 19-22 stating "the present inventors have surprisingly found that, in the case of hydromorphone, a peak

plasma level at between 2-4 hours after administration gives at least 12 hours pain relief…") and the '331 patent (Col 2, lines 21-24 stating "the present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief…"). Each of these patents is prior art to the '042 patent.

109. The Goldie '984 patent and the Goldie '341 patent both issued more than one year prior to the first filing date of the '912 Patent Family.

110. The '331 patent was co-pending for more than one year with the first application of the '912 Patent Family.

111. Disclosure of the '984 Goldie patent would have shown the Examiner that the so-called "surprisingly found" T_{max} range had in fact been known to Purdue and to the world at least one year prior to the filing date of the '331 patent and '912 Patent Family.

112. At the time the application for the '331 patent was filed one of ordinary skill in the art could have been predicted obtaining a T_{max} of 2-4 hours based on the *in vitro* dissolution profile of the claimed oxycodone controlled release formulation.

113. In addition to the Goldie '984 patent, Purdue did not disclose to the PTO other prior art controlled-release formulations that disclosed a T_{max} of 2 to 4.5 hours during 12 hours of pain relief. These include, but are not limited to, Purdue's own MSContin® controlled-release formulation for morphine, and formulations for multiple opioid extended-action controlled release compositions in U.S. Patent No. 4,443,428 which named Benjamin Oshlack as the first inventor.

114. During development of OxyContin® it was Purdue's intent to obtain the same *in vivo* effects as MSContin®. To accomplish this Purdue intentionally copied the

in vitro dissolution profile of the prior art MSContin® even though Purdue had stated to the PTO during prosecution of the '331 patent that *in vitro* dissolution cannot be correlated to *in vivo* effects.

115. Purdue achieved the desired *in vivo* effects, including a T_{max} of 2 to 4.5 hours with four other prior art opioid analgesic drugs.

116. These prior formulations were disclosed in prior art publications, including the '984 Patent (MSContin®, dihydrocodeine), Abstracts of the 1988 International Symposium on Pain Control and Medical Education (codeine); the '428 patent (disclosing multiple opioid extended-action controlled release compositions); and the '341 Patent (hydromorphone).

117. All four of the prior formulation patents of paragraph 114, were known to Purdue during the prosecution of the '331 Patent and the '912 Patent Family, but only the '341 patent was disclosed to the PTO.

118. The other three formulations are not merely "cumulative" of the '341 patent.

119. Four separate Patent Examiners handled these various patents. Examiner Rose handled the '428 patent; Examiner Page handled the '984 and '341 patents; Examiner Spear handled the '331 patent; and Examiner Webman handled the '912 Patent Family. Purdue had a duty to disclose each of these related applications and patents to the PTO.

Terminal Disclaimers:

120. Even after all of Purdue's attempts to gain allowance of the claims of the '331 patent, the Examiner continued to state the '331 patent claims were the same

invention as the Goldie '341 Patent. Euro-Celtique then submitted a Terminal Disclaimer thereby giving up any portion of the patent term for the '331 patent which would extend beyond the expiration date of the Goldie '341 patent. This removed the Goldie '341 patent as a reference against the '331 patent application and subsequently, the '912 Patent Family.

121. During the prosecution of the '912 patent the Examiner rejected the claims for obviousness-type double patenting over claim 1 of the '331 patent. In response, applicants submitted a Terminal Disclaimer over the '331 patent.

122. As the '331 patent was itself disclaimed over the term of the '341 patent, the '912 patent would also expire with the '341 Patent.

123. No terminal disclaimer was requested by the Examiner in the '042 patent.

124. The parent application, the '912 patent was not entitled to the benefit of the priority date of the '331 patent. A terminal disclaimer over the '331 patent application should have been requested by the Examiner.

125. Thus the '042 patent, claiming a method that does not achieve the claimed results, and is obvious in view of the '331 patent, has not yet expired.

126. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support for other and further circumstances constituting inequitable conduct by the applicants.

FIFTH DEFENSE: PATENT MISUSE

127. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Purdue misused the '042 patent in violation of the laws in a manner as to render the patent unenforceable.

128. Purdue is aware that the '042 patent is invalid and was obtained fraudulently by inequitable conduct.

129. Purdue is aware that the method claimed in the '042 patent for the stated purpose of "reducing the daily dosage" is inaccurate and unachievable.

130. Purdue submitted the '042 patent to the FDA to be listed in the Orange Book. Purdue's efforts to enforce the '042 patent, by infringement suits and by listing the patent in the Orange Book, constitute patent misuse.

COUNTERCLAIMS

Apotex, Inc. and Apotex Corp. set forth the following affirmative and other counterclaims. In each Counterclaim, Apotex adopts by references, repeats, and realleges its responses in paragraphs 1 - 19 and its affirmative statements in paragraphs 20 - 130 above as if fully set forth therein.

NATURE OF THE ACTION

1. Apotex Inc. and Apotex Corp's claims against counterclaim defendants Purdue Pharma., L.P., P.F. Laboratories, Inc., and Purdue Pharmaceuticals, L.P. ("Counterclaim Defendants" or "Purdue") arises out of Purdue's inequitable conduct in the PTO and its overall scheme to obtain and further its illegal monopoly and injure competition.

2. Counterclaim defendants have knowingly and intentionally made and continue to make affirmative misrepresentations and fraudulent statements, as well as withhold material information, in order to maintain the validity of the '042 patent.

PARTIES AND JURISDICTION

3. Counterclaim plaintiff Apotex, Inc. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. Counterclaim plaintiff Apotex, Corp. is a Canadian corporation having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that counterclaim defendant Purdue Pharma., L.P. is a is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard Stamford, Connecticut 06901-3431.

6. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that counterclaim defendant P.F. Laboratories Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey 07512.

7. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that counterclaim defendant Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893.

8. This Court has jurisdiction over the subject matter under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et. seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA"); the Antitrust Laws of the United States, including, *inter alia*, the Sherman Antitrust Act, 15 U.S.C. § 2; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has subject matter jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1332, 1337, 1338(a), and 2201.

10. Venue and personal jurisdiction are proper in this district because Purdue, *inter alia*, is subject to personal jurisdiction and has submitted itself to the jurisdiction of this Court.

PURDUE'S DRUG PRODUCT

11. Purdue is the owner of a number of patents listed in the Orange Book for the drug oxycodone, which is sold by Purdue under the trademark Oxycontin®.

12. Oxycontin® is an opioid analgesic. On December 12, 1995, Counterclaim defendants received approval from the FDA for a controlled-release oxycodone branded drug, Oxycontin® Controlled-Release Tablets, in 10, 20 and 40 mg dosage strengths.

13. Purdue has alleged that it is the lawful owners of all right, title, and interest in and to U.S. Patent No. 5,508,042 (the '042 patent) , including all right to sue and to recover for past infringement thereof. Purdue has further alleged that the '042 patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (Approved Drug Products With Therapeutic Equivalence Evaluation) as covering OxyContin® and contains one or more claims covering OxyContin®'s method of use.

14. Apotex, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 78-840 to the FDA to market a proposed generic version of Oxycontin®.

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Purdue that the '042 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the new drug for which ANDA No.78-840 was submitted.

16. A real, actual, and justiciable controversy exists between Apotex, Inc. and Apotex Corp. on one side and Purdue on the other side regarding *inter alia* the invalidity of the '042 patent and Apotex, Inc.'s and Apotex Corp.'s non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2005).

COUNT I: DECLARATION OF INVALIDITY

17. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific responses to paragraphs 1 - 19 and affirmative statements in paragraphs 20 - 130 of the Complaint above as if fully set forth therein.

18. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific averments made in paragraphs 1-17 of this Counterclaim as if fully set forth therein.

19. The ’042 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including, but not limited to, failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

. **COUNT II: DECLARATION OF ANTICIPATION**

20. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific responses to paragraphs 1 - 19 and affirmative statements in paragraphs 20 - 130 of the Complaint above as if fully set forth therein.

21. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific averments made in paragraphs 1-20 of this Counterclaim as if fully set forth therein.

22. The ’042 patent issued April 16, 1996, from Patent Application No. 467,584, filed June 6, 1995, as a divisional application of Patent Application No. 81,302, filed November 25, 1992, which issued as U.S. Patent No. 5,549,912 and was a continuation-in-part of Patent Application Serial No. 07/800,509 filed November 27, 1991 and issued November 30, 1993 as U.S. Patent 5,266,331.

23. The ‘042 patent is invalid under 35 U.S.C. § 102 over prior art including, but not limited to, the prior art cited in the Affirmative Defenses above.

COUNT III: DECLARATION OF OBVIOUSNESS

24. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific responses to paragraphs 1 - 19 and affirmative statements in paragraphs 20 - 130 of the Complaint above as if fully set forth therein.

25. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific averments made in paragraphs 1-24 of this Counterclaim as if fully set forth therein.

26. The scope and content of the prior art includes, but is not limited to, the prior art cited in the Affirmative defenses above.

27. The differences between the subject matter claimed in the '042 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

COUNT IV: DECLARATION OF UNENFORCEABILITY

28. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific responses to paragraphs 1 - 19 and affirmative statements in paragraphs 20 - 130 of the Complaint above as if fully set forth therein.

29. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific averments made in paragraphs 1-24 of this Counterclaim as if fully set forth therein.

30. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '042 patent misled the PTO about the properties of the invention claimed therein.

31. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '042 patent intentionally failed to disclose material prior art to the PTO.

32. More particular details of Purdue's inequitable conduct are described in paragraphs 23-126 above.

33. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the PTO.

34. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for other circumstances constituting inequitable conduct by the applicants.

COUNT V: ATTEMPTED MONOPOLIZATION

35. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific responses to paragraphs 1 - 19 and affirmative statements in paragraphs 20 - 130 of the Complaint above as if fully set forth therein.

36. Apotex, Inc. and Apotex, Corp. adopt by reference, repeat and reallege their specific averments made in paragraphs 1-35 of this Counterclaim as if fully set forth therein.

The Drug Product and Market

37. The entry of generic drugs into the market creates competition, and consequently, lower drug prices.

38. The fewer generic competitors there are in the market, the higher the price for a drug can be maintained.

39. The relevant geographic market in this case is the United States.

40. The relevant product market in this case is controlled-release oxycodone for the treatment of pain.

41. Purdue controls 100% of the relevant market. Consequently, Purdue has monopoly power in the relevant market through, *inter alia*, its ability to raise and/or control prices and/or exclude competition and/or restrict output without losing substantial business.

42. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support for the proposition that Purdue does not want to compete with generic drug manufacturers in the relevant market.

Purdue's Anti-Competitive Scheme

43. Purdue engaged in a pattern and practice of anti-competitive conduct with the intent of preventing or delaying Apotex Corp. from marketing a competing controlled release Oxycodone product for the treatment of pain.

44. Purdue intentionally made misrepresentations to the PTO and intentionally withheld material information from the PTO in order to cause the PTO to issue, among other things, the '042 patent. But for Purdue's intentional misrepresentations and intentional withholding of information, the '042 patent would not have issued.

45. Despite Purdue's knowledge that the '042 patent was obtained through fraud and is therefore unenforceable, Purdue caused the '042 patent to become listed, and remain listed, in the Orange Book.

46. The existence of the '042 patent creates significant barriers to entry into the relevant market.

47. Purdue's overall scheme to obtain and maintain its illegal monopoly over the relevant market is evidenced by, among other things, Purdue's intentional material misrepresentations to the PTO during the prosecution of the '042 patent and, knowing that the '042 patent was invalid, unenforceable, and/or not infringed, filing multiple patent infringement suits over the '042 patent and other fraudulently obtained patents to keep generic drug manufacturers out of the market.

48. Purdue's lawsuits against Apotex, Inc., Apotex Corp. and other generic drug makers are based on fraudulently-obtained patents, including the '042 patent, and constitute sham litigation and Walker Process fraud.

49. Purdue has entered into a contract, combination, or conspiracy to monopolize the relevant market and has engaged in an overall scheme to wrongfully monopolize the relevant market.

Antitrust Injury and Damages

50. Apotex, Inc. produces more than 260 generic pharmaceuticals in over 4000 dosages and formats to over 115 countries around the world.

51. Apotex, Inc. expended considerable effort and resources to develop a generic version of controlled release oxycodone that was therapeutically equivalent or bio-equivalent to Purdue's Oxycontin®.

52. Purdue's anti-competitive acts are harming competition and causing injury to Apotex, Inc. by preventing the FDA from granting final approval that would allow Apotex, Inc. to bring a more affordable version of controlled-release oxycodone to market. As a result, healthcare providers and patients are forced to pay prices set by Purdue in its monopoly.

53. Purdue's anti-competitive scheme injured Apotex, Inc. and Apotex Corp. when Apotex, Inc. and Apotex Corp. were sued by Purdue for patent infringement in the District of Delaware and in the Southern District of New York in September 2007, instituting a 30-month statutory stay. The 30-month stay will delay Apotex Corp's entry into the relevant market, because the FDA cannot approve the marketing of Apotex, Inc.'s drug before either the resolution of litigation or the end of the 30 month stay.

54. Apotex, Inc. and Apotex Corp. would have received approval and begun marketing prior to the end of the 30 month stay but for Purdue's exclusionary conduct.

55. Purdue's anti-competitive acts illegally restrain Apotex, Inc. and Apotex Corp. from marketing their proposed drug product, and caused and continues to cause irreparable injury to Apotex, Inc. and Apotex Corp. in other ways, including, but not limited to, the expenses of the current litigation, which is based on a fraudulently-procured patent; the loss of millions of dollars of lost profits from the sale of generic controlled release oxycodone products; the loss of the ability to develop new customer relationships; and the loss of valuable goodwill due to being unable to participate in the relevant market. These injuries are directly attributable to Purdue's illegal anti-competitive conduct.

56. Purdue's illegal, anti-competitive conduct occurred in, and has a substantial effect on, interstate commerce. Further, this conduct injures competition.

57. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that the Purdue engaged in actions constituting illegal monopolization in violation of, *inter alia*, 15 U.S.C. § 1, 15 U.S.C. § 2, and/or 15 U.S.C. § 4.

58. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that, *inter alia*, Purdue's actions continue to injure Apotex, Inc. and Apotex Corp., therefore Apotex, Inc. and Apotex Corp. are entitled to injunctive relief under 15 U.S.C. § 26.

PRAYER FOR RELIEF

WHEREFORE, Apotex, Inc. and Apotex Corp. pray for judgment:

a. Finding that the '042 patent is invalid and unenforceable;

b. Finding that the '042 patent is not infringed;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding Apotex treble its actual damages incurred by Purdue's violation of the antitrust laws;

e. Awarding to Apotex its costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp demand trial by jury for all issues triable by jury as a matter of right.

Respectfully Submitted,

Date: November 2, 2007 By: /s/ Robert B. Breisblatt

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